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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Medical Devices Dispute Resolution Panel of the Medical Devices Advisory

Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

General Function of the Panel: To provide advice and recommendations to the agency on scientific disputes between the Center for Devices and Radiological Health and sponsors, applicants, and manufacturers.

Date and Time: The meeting will be held on October 31, 2000, 1 p.m. to 4 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Les S. Weinstein, Center for Devices and Radiological Health (HFZ-5), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, e-mail: lsw@cdrh.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 10232. Please call the Information Line for up-to-date information on this meeting.

Agenda: The members of the newly established Medical Devices Dispute Resolution Panel will be introduced to the public and will hear presentations by FDA staff on the purpose of the panel and its role in dispute resolution.

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Procedure: Interested persons may present data, information, or views, orally or in writing, on issues regarding resolving scientific disputes concerning medical devices and on the role of this panel. Written submissions may be made to the contact person by October 25, 2000. Oral presentations from the public will be scheduled between approximately 2 p.m. and 4 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 25, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of

proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the October 31, 2000, Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 10-18-00

October 18, 2000

Linda A. Suydam

Senior Associate Commissioner

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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